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EXAMINER

ROSE, SHEP K

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1614

DATE MAILED: 09/10/2003

15

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/035320

Applicant(s)

BARA BOCAK-Jol

Examiner

SIMP

ROSE

Group Art Unit

1614

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

## Status

- ☒ Responsive to communication(s) filed on JUNE 23 2003
- ☐ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

## Disposition of Claims

- ☒ Claim(s) 1, 2, 4 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 2, 4 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

## Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

The finality of the January 10, 2003 office action is hereby withdrawn in view of an issue of 35 USC 112 (2<sup>nd</sup> Par) of claims 6 to 14, 16 to 18 and 22 with respect to the "metes and bounds" of these vague and indefinite claims so the public can avoid infringing them.

Herein, according to the specification disclosure, the written descriptions has 100% of the triclosan in a coating on the insoluble chewing gum core, which contains no triclosan whatsoever; the emulsion of triclosan is only enabled herein as a coating on the chewing gum.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6 to 14, 16 to 18 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 depends on claim 15 which claim recites no gum, "no piece of gum"; is claim 16 intended?

According to the recitals of this specification there is an emulsifier in the insoluble chewing gum base (see page 6, lines 27-28), which also contains a water soluble portion, emulsifier and surfactant, but the triclosan is never incorporated therein; the triclosan is only in the pellet chewing gum coating on the insoluble chewing gum base, as see page 10 lines 10 and 12 (with hydroxylated lecithin emulsifier).

Page 11, lines 10 to 12 explicitly informs the reader that the addition of triclosan into the chewing gum base itself "failed to provide a benefit".

Claims 6 to 14 16 to 18 and 22 encompass triclosan emulsifier and surfactant in the chewing gum base itself, by failing to recite that the triclosan must be entirely in the coating on the chewing gum. "The public cannot determine the "metes and bounds of these claims so as to avoid infringement of them".

The meter and bounds or encompassed "scope" of these claims are "vague and indefinite" (35 USC 112, 2<sup>nd</sup> par.).

USPTO examiners are tasked to reject on 35 USC 112 (2<sup>nd</sup>) Par grounds of rejection when the public cannot determine the "metes and bounds" of the patent's claims and take steps to avoid infringement, according to.

Stephen Kunin's (Deputy Commissioner for Patent Examination Policy) January 17, 2002 Memorandum, effective immediately, [(Clarifying Office Policy with respect to rejections made under 35 U.S.C. 112, second paragraph). Advance notice of changes to MPEP 2173.02,].

Commissioner Kunin's January 17, 2002 Memorandum states that in reviewing a claim for compliance with 35 U.S.C. 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim provides clear warning to others as to what constitutes infringement of the patent and therefore serves the notice function required by 35 USC 112, second paragraph, and, if the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, a rejection of the claim under 35 U.S.C. 112, second paragraph would be appropriate. The examiner must consider

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the claims as a whole to determine whether or not the claim apprises one of ordinary skill in the art of its "metes and bounds".

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Memorandum

Date: January 17, 2003

TO: Technology Center Directors  
Patent Examining Corps

From: Stephen G. Kunin  
Deputy Commissioner for Patent Examination Policy

Subject: Advance notice of changes to MPEP § 2173.02 clarifying Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph in view of the Supreme Court holding in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 62 USPQ 2d 1705 (2002)

This memorandum clarifies Office policy with respect to rejections made under 35 U.S.C. § 112, second paragraph. The guidance provided herein is effective immediately and should be applied by all Office personnel. These changes will be published in the next revision of the MPEP.

As noted in MPEP § 217.02, during examination of claims for compliance with the requirement for definiteness under 35 U.S.C. § 112, second paragraph, some latitude in

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the manner of expression and the aptness of terms should be permitted even though the claim language is not as precise as the examiner might desire. In reviewing a claim for compliance with 35 U.S.C. § 112, second paragraph, the examiner must consider the claim as a whole to determine whether the claim apprises one of ordinary skill in the art of its scope and, therefore, serves the notice function required by 35 U.S.C. § 112, second paragraph by providing clear warning to others as to what constitutes infringement of the patent. See *Solomon v. Kimberly-Clark Corp.*, 216 F.3d 1372, 1379, 55 USPQ2d 1279, 1283 (Fed. Cir. 2000). If the language of the claim is such that a person of ordinary skill in the art could not interpret the metes and bounds of the claim so as to understand how to avoid infringement, as rejection of the claim under 35 U.S.C. § 112, second paragraph would be appropriate. See *Morton Int'l, Inc. v. Cardinal Chemical Co.*, 5 F.3d 1464, 1470, 28 USPQ2d 1190, 1195 (Fed. Cir. 1993). Office policy is not to employ per se rules to make technical rejection. Examples of claim language which have been held to be indefinite set forth in MPEP § 2173.05(d) are fact specific and should not be applied as a per se rule. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety travel chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ 2d 1081, 1088 (Fed. Cir. 1986).

If upon review of a claim in its entirety, the examiner concludes that a rejection under 35 U.S.C. § 112, second paragraph is appropriate, such as rejection should be made and

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an analysis as to why the phrase(s) used in the claim is "vague and indefinite" should be included in the Office action.

By providing an explanation as to the action taken, the examiner will enhance the clarity of the prosecution history record. As noted by the Supreme Court in *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 122 S. Ct. 1831, 1838, 62 USPQ2d 1705, 1710 (2002), a clear and complete prosecution file record is important. With respect to amendments made to comply with the requirements of 35 U.S.C. § 112, the court stated that "[i]f a § 112 amendment is truly cosmetic, then it would not narrow the patent's scope or raise an estoppel. On the other hand, if a § 112 amendment is necessary and narrows the patent's scope—even if only for the purpose of better description—estoppel may apply." *Id.*, at 1840, 62 USPQ2d at 1712. The court further stated the "when the court is unable to determine the purpose underlying a narrowing amendment – and hence a rationale for limiting the estoppel to the surrender of particular equivalents—the court should presume that the patentee surrendered all subject matter between the broader and the narrower language... the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question." *Id.*, at 1842, 62 USPQ2d at 1713. Thus, when, whenever possible, the examiner should make the record clear by providing explicit reasoning for making or withdrawing any rejection related to 35 U.S.C. § 112, second paragraph.

As noted above, the public cannot determine the "metes and bounds" of these claims.

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Commonly assigned (Wrigley) patents with claims to medicament (broadly) in coatings on chewing gum, namely: U.S. 6,355,265 (claims 1 and 10); U.S. 6,350,480 (claims 10, 12 and 29); U.S. 6,322,806 (claims 1, 10, 19, 28); U.S. 6,290,985 (claims 1, 9, 12, 17, 26) raise an issue of obviousness-type double patenting.

Applicants July 22, 2002 response, after noting that claims 1 to 22 have been rejected on allowed claims 28 to 32 of parent application Serial no. 09/453,383 (now U.S. Patent 6436369) on the ground of non-statutory double patenting, states that a terminal disclaimer" will be filed upon issuance of copending application 09/453,383, which in fact issued August 20, 2002 but the USPTO policy practice and procedure is to reject copending applications for obviousness-type double patenting, and not to wait until they issue as patents. The terminal disclaimer has been filed and accepted by the USPTO.

Applicants July 22, 2002 response notes that claims 1, 2, 4, 5, 15, 19 and 23 have been rejected by Libin (I) U.S. 5,236,699 as anticipated, 35 USC 102 (B), the USPTO Examiner following the MPEP to establish by extrinsic evidence, that Libin describes antiplaque triclosan with cetylpyridinium chloride surfactant as well as with two (2) emulsifying agents: Tweens 20 and Pluronic L64 surfactants, see Merck Index entries for both. The MPEP Sections have been cited to applicant.

Applicants' counsel's responsive remarks, seemingly questions relevance on the MPEP sections permitting the USPTO Examiner to rely on Merck Index to establish the fact that Libin who has two emulsifiers Tween 20 and Pluronic L64 with the same



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triclosan and the same cetyl pyridinium chloride surfactant as his antiplaque composition, can be an anticipation, 35 U.S.C. 102.

Claims 1 to 5, 15, 19, 20, 21, 23 and 24 which do not recite or require any chewing gum, are drawn to antiplaque compositions and oral methods for reducing plaque, wherein the composition comprises (A) triclosan as the antiplaque agent, (B) an emulsifier, and (C) a surfactant, which, in dependent claims 2 and 19 is cetylpyridinium chloride, in dependent claims 3 and 20 there is 3% to 30% triclosan, in dependent claims 4 and 21, there is 0.1 to 10% surfactant, in dependent claim 5 there is (D) water and (E) a solvent for the tri-closan.

Here, the Examiner can properly rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is an anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant.

Claims 1, 2, 4, 5, 15, 19 and 23 are now rejected under 35 USC 103, and stand rejected under 35 U.S.C. § 102(b) as being anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride surfactant a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5

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to 2%, a polysorbate pharmaceutical emulsifier and surfactant dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier, (according to Merck Index, entry 7722), said combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipates claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

Claims 3, 4, 20, 21 and 24 are rejected as obvious, under 35 U.S.C. 103 over Libin: they differ from Libin (I), in requiring 3% (a) Triclosan instead of 0.05%, and while the chewing gum claims 6-14 and 16-18 are not described, there is clearly only an obvious difference from a mouthwash in Libin in the toothpaste or gel of claim 24.

Claims 6 to 13, 15 to 18 and 22 recite a chewing gum wherein triclosan, an emulsifier and a surfactant are "in a water soluble portion", which only in claim 14, in part, can be a coating of the pellet of the pellet chewing gum recited only in claim 13, and, and only in claim 22 does each piece of gum include 1mg to 6 mg of triclosan. In none of these triclosan chewing gum claims is it recited and required that all of the triclosan, surfactant and emulsifier be a coating on the chewing gum, or that it be a coating on pellet chewing gum, or that there be 1 mg. To 6 mg. of triclosan in a coating on chewing gum, or on pellet chewing gum. Only in claim 13 is the chewing gum in

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pellet form, and only in claim 14 is the triclosan, in part, in a coating of the pellet with an emulsifier and surfactant.

The term "a water soluble portion" recited in claim 6, in which the triclosan, an emulsifier and surfactant are "included", (although perhaps meant to imply a water soluble coating on the chewing gum) reads on the chewing gum base vehicle, per se, since Hill, U.S. 5380530, at page 8, lines 63 to 68 states the fact that slab chewing gum base is more than 75% water soluble materials, such as sugars, sugar substitutes corn syrup and the like.

Claims 7 to 12 depend on claim 6, and read on triclosan in the chewing gum base of a slab or stick or sheet of chewing gum, which customarily have emulsifiers and surfactants.

Claims 1, 2, 5-7, 9, 13-16 and 19 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Hill U.S. 5,380,530A, 10 January 1995, taken with Libin (I) (details as noted above), it being within the level of skill of the art to replace a single surfactant-emulsifier with a combination of two of them, as described by Libin (I), (details as noted above).

Hill describes an anti-plaque emulsion coating on chewing gum (same as herein) comprising (a) an emulsifying agent (column 10, lines 51-55); (b) Triclosan (same as herein) (column 9, line 58, column 15, line 26, in Example 17, Table II, 0.2 to 1.0%, and claim 2; and (c) cetyl pyridinium chloride (same as herein) (column 15, line 30 and claim 2; and (d) a surfactant, claim 9, column 10, lines 11-50; (TABLE I, "PLURONICS", etc.)

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and (e) chewing gum plasticizer softening agents which happen to be applicants' "emulsifiers" according to the recitals of this specification at page 6, lines 22-28 and Example 2 page 10: Hydroxylated lecithin in the Example, lecithin, glycerol monostearate, or other mono or diglycerides, Hill describing applicants' emulsifiers acetylated monoglycerol triacetate, glycerol diacetate, and lecithin, 0.4 to 0.6% at column 19, line 65 to column 20, line 11.

Hill (details as noted above) emulsion coats triclosan on chewing gum (same as herein) and renders obvious (35 U.S.C. § 103) claims 1, 2, 5-7, 9, 13-16, and 19 the rejection being made under 35 U.S.C. § 103, but differs from, and does not explicitly anticipate or describe claims 3, 10, 20 and 22 in the percentage of Triclosan (1% versus 3%), and differs from claims 4, 11 and 21 in not specifying the percentage of surfactant in the anti-plaque Triclosan chewing gum coating, however, clearly, it being within the level of skill of the art to replace equivalent percentages of a single surfactant-emulsifier with percentages of a combination of two of them, as described by Libin (I), (details as noted above), the Examiner relying on Merck Index extrinsic evidence to establish that claim encompassed surfactants of Hill are known as emulsifiers as well.

Hill, according to applicants' counsel's remarks does not anticipate these claims under 35 U.S.C. § 102 because it is argued, herein a single surfactant and emulsifier are employed with Triclosan to emulsion coat the chewing gum, but to interchange equivalent percentages of a combination of a surfactant and an emulsifier to attain the same goal is clearly prima facie obvious 35 U.S.C. § 103.

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Hill emulsion coats triclosan and cetylpyridinium chloride (same as herein) onto "slabs" sheets of chewing gum base, (in contrast to onto candy coated gum nuggets (col. 9, lines 1 to 15) or placing his claimed emulsions into liquid center chewing gums or into chewing gum base mixes as in Wrigley chewing gums (col. 8, lines 38-68) which are more than 75% water soluble materials such as sugars, sugar substitutes, corn syrup, etc.) Claim 6 herein recites such water-soluble portions, of the chewing gum base, to include the triclosan.

Hill explicitly applies his emulsion coatings of triclosan, and/or cetylpyridinium chloride (same as herein) onto chewing gum in sheet or slab form (column 21, lines 10 to 22, column 22, line 19 to 22, 28, 29, 47, 48 onto a sheet of gum, emulsion coating on the chewing gum sheet, sheet of chewing gum, column 23 lines 1, 2 chewing gum sheet.

The term "chewing gum" in applicants' claims 6 to 12, 16 to 18 and 22 encompasses Hill's preferred enabled examples of slab or sheet "slabs" of chewing gum.

Only in applicants' dependent claims 13 and 14 is the chewing gum defined as in pellet form, and only in dependent claim 14 is the triclosan emulsion chewing gum coating (Same as Hill's), and only in part, a coating of the pellet.

"Pellet" chewing gum may be the non-preferred "costly alternative" to Hill's desired slab forms of chewing gum, set forth by Hill at column 9, lines 1 to 16, in contrast to chewing gum wherein medicament is in a candy coating on a gum nugget or

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center, commonly called "candy coated gum", but these are clearly contemplated by Hill as encompassed by the triclosan and cetylpyridinium emulsion coating of "chewing gum" in claim 2 of Hill, as see column 23, lines 6 to 10, in any desired mg quantity, on a wide range of piece size and shape, "mints", sticks, slabs, lines 45 to 52 modifications are with the scope of the claims.

Claims 1-7, 9-11, 13, 15-17 and 19-21 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Anderson et al., U.S. 5,487,902A, 30 January 1996, who describe (column 11 line 58 to column 12 line 5) any chewing gum (candy coated "bits" or sticks) with active agents to be chewed for 2 to 30 minutes, said chewing gums including: (a) Triclosan (column 9, line 24; 0.1 to 10% at column 10, line 26 and 0.01 to 30% at column 12, line 53; (b) cetylpyridinium chloride at column 8, lines 54-55; and solubilized with emulsifying solubilizing surfactants "AT LEAST ONE" and "A COMBINATION OF SEVERAL" at column 6, lines 21-22 and claim 12; (c) solubilizers-surfactants (all known and approved for use as emulsifiers) (column 5, line 57 to column 6, line 24, 1% to 10% at column 10, lines 56-57, column 12, line 55 and claim 4; (d) emulsifying active agent solubilizing agents, column 7, lines 8-26, 0 to 12%.

Anderson et al. anticipate claims 1-7, 9-11, 13, 15-17, and 19-21 but does not explicitly specify a weight of 1 mg to 6 mg of Triclosan per piece of gum as in claims 12 and 22, and do not explicitly state to chew the gum three times per day as in claim 18, and beyond chewing gum, do not further describe a mouthwash, toothpaste or gel as in claims 23 and 24.

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Applicants' counsel's remarks have been considered but are seen to have inadvertently overlooked the terms "AT LEAST ONE" and A COMBINATION OF SEVERAL" (c) solubilizer surfactants known as emulsifiers as well as the (d) emulsifiers employed by Anderson in chewing gum base with (a) Triclosan and (b) cetylpyridinium chloride, which in the claims herein are neither recited to be in a coating on the gum, or inside the chewing gum base center itself, while applicants' only claimed coating, in claim 14 "IN PART" unfortunately does not recite or require that 100% of the Triclosan is in the pellet coating on the pellet center, there being "NO TRICLOSAN WHATSOEVER" in applicants' described and enabled chewing gum base or gum pellet center as a careful review of the specification will establish to anyone's satisfaction.

The remarks and arguments by applicants' attorney (who has not been qualified as an expert) are not considered to be the opinion of an expert, see In re Schulze 145 USPQ 716 "... Argument of counsel cannot take the place of objective evidence ...". They certainly reveal a lack of recognition that claims encompassed surfactants function as emulsifiers. There is no Rule 132 Declaration of any expert by applicants who are considered to be skilled in the art to buttress or to support the argument, which is unsubstantiated. Counsel's remarks have been considered, but are not seen as a substitute for a Rule 132 Declaration of an expert, when counsel is arguing technical facts. Attorney argument is not evidence, unless it is an admission. See: In re De Blauwe, 222 USPQ 191, 196; Meitzner v. Mindick, 193 USPQ 17, 22, In re Pearson, 181 USPQ 641, 646, In re Lindner, 173 USPQ 356, 358; In re Schalze, 145 USPQ 716,

718; In re Cole, 140 USPQ 230, 233, and In re Walters, 77 USPQ 609, 610. The following arguments have been made in the remarks:

"LIBIN" does not describe the use of an emulsifier ..., "... to overcome the emulsifier element deficiency in Libin ..." In this regard, Libin does not disclose an emulsifier..." "... Neither Hill nor Anderson discloses the use of a nonionic surfactant as an emulsifier ..."; "... Clearly the Hill and Anderson references do not teach the use of a nonionic surfactant as an emulsifier ...", "indeed Hill discloses a variety of surfactants but not that such surfactants may also function as an emulsifier". "Thus combining the teaching of Libin with that of Hill would fail to arrive at applicants' claimed invention because the required emulsifier element would be missing".

Applicant's arguments have been fully considered, but are clearly erroneous. Libin's Tweens 20 and Pluronics L64 are not only described by Merck Index as emulsifying agents, they are also described by Anderson et al as apt solubilizing surfactants for active agents in chewing gum known to be emulsifiers. Anderson et al describe both of Libin's surfactant Tweens and Pluronics in Examples as solubilizing surfactants known for use as emulsifiers. Both Hill and Anderson do in fact teach the use of non-ionic surfactants as emulsifiers. See: In Hill, column 10 line 11, suitable surfactants and emulsifiers for use in the present emulsion coating for gum include: ("Tweens") at lines 49 and 50, line 23 to 25 (polyoxyethylene derivatives of sorbitan esters) ("Pluronics" mentioned at lines 45 to 49), Table I, columns 11 and 12, (both in claim 9 of Hill). Anderson et al teach both of Libin's Pluronic and Tween surfactants to be known for use as emulsifiers (See column 6, lines 1 to 24 as well as Tweens in



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Examples 48 to 75, and 100 to 103, 113, 146 Pluronics in Examples 76 to 87, and note both in Anderson et al's claims 4 and 5.

Applicants' attorney's arguments do not reflect USPTO practice. The remarks include: As previously argued, Libin I fails to disclose the emulsion features of independent Claims 1 and 15. Nowhere does Libin I disclose an emulsion or its use in relation to its anti-plaque mouth rinse. Applicants question how the Patent Office can rely on Libin I where Libin I discloses a solubilizer that is utilized in a sufficient amount to solubilize triclosan. See, Libin I, Claim 1, col. 1 at lines 53-60. In this regard, Libin I emphasizes solubilizing, not emulsifying triclosan. Moreover, as discussed above the Patent Office is not permitted to expand the meaning of the solubilizer disclosed in Libin I to also mean an emulsifier. It is clear that Libin I is using Tween 20 only as a solubilizer not as an emulsifier. While it is perhaps arguable that Tween 20 is also useful as an emulsifier, the reference clearly does not disclose using it as one. Moreover, the Examiner is not permitted to use extrinsic evidence to characterize Tween 20 as an emulsifier when the reference is only describing it as a solubilizer. As noted above, extrinsic evidence is not allowable to "expand the meaning of terms in a reference".

Applicants' attorney's remarks on Anderson et al in advertently overlook the above noted teaching of Anderson et al to employ solubilizing surfactants known to be useful emulsifiers. It is argued:

In the Office Action, claims 1-7, 9-11, 13, 15-17 and 19-21 are rejected under 35 U.S.C. § 102(b) as being anticipated by Andersen. The Patent Office essentially asserts that Andersen discloses each and every feature of the rejected claims.

Applicants submit that the Patent Office again incorrectly relies on Andersen as an anticipatory reference. The Examiner's position that "they do not have to state that their surfactants are emulsifiers, if extrinsic evidence (Merck Index) establishes that such encompassed species of nonionic surfactants to be used are emulsifiers." Is clearly contrary to established law. See, Office Action, p. 89. It is argued:

Andersen, like Libin I, requires a solubilizing agent to solubilize the active agent, such as triclosan, in order to control the release of said active agent. See, Andersen, Claim 1, col. 10 at line 57-61. Further, Andersen clearly makes a distinction between the uses of an emulsifier as compared to solubilizers. Again, while it might be arguable that these solubilizers may also be emulsifiers, it is clearly not described as so in the Anderson reference. (This argument is contrary to Anderson to use solubilizer known as emulsifiers). Moreover, extrinsic evidence is "not permitted" to expand the meaning of terms in a reference.

The Examiner properly relies on Merck Index as extrinsic evidence showing that those of ordinary skill in that art know that the nonionic Tween and Pluronic surfactants of Libin, Hill and Anderson function as emulsifiers. See MPEP § 2131.01 (d) and MPEP § 2112-2113 for case law on inherency. See: Atlas Powder versus Ireco, 51 USPQ 2d 1943.

The legal basis for an inherency rejection, one that can properly be made under 35 U.S.C. § 102/103, is set forth in MPEP § 2112-2112.02 citing In re Fitzgerald et al., 205 USPQ 594. When the reference discloses all the limitations of a claim except a property or function, whether or not the reference inherently possesses properties or renders obvious the claimed invention, there is basis for shifting the burden of proof to applicant. Also, MPEP § 2183-2184, when the reference teaches all the claim limitations except a claimed element, an examiner is not certain whether the element disclosed in the reference is an equivalent to the claimed element and therefore anticipated, or whether the prior art element is an obvious variant of the claimed element.

Here, the Examiner can rely on extrinsic evidence (Merck Index) to establish with certainty that that Libin (I) U.S. 5,236,699A, 17 August 1993, a reference introduced into the record by applicants on their PTO-1449 IDS, is anticipation, under 35 U.S.C. § 102, of claims 1, 2, 4, 5, 15, 19 and 23 because 2 (two) of the surfactants employed with Libin's enhanced anti-plaque combination of (a) Triclosan and (b) cetylpyridinium chloride, are described by Merck Index as emulsifiers, (c) Tween 20 surfactant, and (d) Pluronic L64 surfactant. These claims are clearly anticipated by Libin (I) U.S. 5,236,699A, 17 August 1993, who describes an enhanced activity anti-plaque aqueous alcoholic vehicle for mouthwash, comprised of: (a) Triclosan, a water insoluble anti-plaque agent, 0.01 to 0.05%; (b) cetylpyridinium chloride, a water soluble antiplaque agent (it's a cationic surfactant as well), 0.020% to 0.030%; (c) Tween 20, a triclosan solubilizer, 0.5 to 2%, a polysorbate pharmaceutical emulsifier and surfactant

dispersing agent, (according to Merck Index entry 7742); (d) Pluronic L64, 10%, as a foaming agent, which is an emulsifier, (according to Merck Index, entry 7722), said combined agent coaction of (a) and (b) to afford highly effective enhanced antibacterial activity against dental plaque, (e) water, 67%; and (f) alcohol, 18%.

Libin fully anticipated claims 1, 2, 4, 5, 15, 19 and 23 (mouthwash) under 35 U.S.C. § 102, since these claims either recite no percentage concentration levels for any of the components, and the surfactant percentages of claim 4 are described, as noted above.

In an attempt to advance the prosecution of this application to a more timely issue, the Examiner can properly substantiate in the record the well known fact, as a matter of common knowledge in the art, that the two (2) surfactants of LIBIN (I) function as emulsifiers according to Merck Index. The claims that had been rejected under 35 U.S.C. § N 102/103 on Libin alone on a theory of inherency, based on this well known substantiated fact MPEP § 706.02 (a), 707.07 (f) can properly be rejected either on 35 U.S.C. § 102 or on 35 U.S.C. § 103.

While applicants herein have 100% of the Triclosan and cetylpyridinium chloride in the pellet outer coatings, and 0% of each inside their chewing gum base center, claims 6, 13 and 14 are clearly not commensurate in scope with applicants' disclosed enabled and described invention, but the broadest reasonable interpretation of these claims metes and bounds must be given.

Claim 1 does not recite or even require that --said anti-plaque emulsion comprise a coating of the pellet chewing gum in pellet form--.

Claim 1 does not define the emulsion as defined in the specification on page 6, lines 22-28 and Example 2 on page 5 as said emulsifier being selected from the Markush group consisting of --hydroxylated lecithin, lecithin, glycerol monostearate, other mono-and diglycerides--. The term "surfactant" in claim 1 clearly encompasses known species of surfactants which function inherently and have been described in the prior art as emulsifiers, by Anderson et al, (as noted above), and by Hill (as noted above).

The Courts have held that there is no requirement that those of ordinary skill in the art know of the inherent property. See MPEP 2131.01(d) and MPEP § 2112-§2113 for case law on inherency. Also note that the critical date of extrinsic evidence showing a universal fact need not antedate the filing date. See MPEP § 2124.<

Atlas Powder Co. C. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999)

"Artisans of ordinary skill may not recognize the inherent characteristics or functioning of the prior art ... however, the discovery of a previously unappreciated property of a prior art composition patentably new to the discover. "The Court further held that "this same reasoning holds true when it is not a property but an ingredient which is inherently contained in the prior art".

Mehl/Biophile International Corp. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999)

Thus viewed as a whole, the Polla disclosure shows that the "natural result flowing from the operation as taught would result in alignment of the laser light over the hair follicle, as claimed." This was true even though Polla did not mention the goal of hair removal. Therefore, the Court held that the '192 patent was invalid as anticipated.

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may be an inherent characteristic of the prior art, it has the authority to require the applicant to prove that the subject matter shown in the prior art does not possess the characteristics relied on. In re Schreiber, 44 USPQ2d 1429 (Fed. Cir. 1997).

Products of identical chemical composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present. In re Spada 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). See MPEP 2112.01.

INHERENCY OF METHODS. Ex parte Novitski 26 USPQ 1389 (BPAI 1993)

Meh/Biophile International Corp. V. Milgraum. 52 USPQ2d 1303 (Fed. Cir. 1999)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shep Rose whose telephone number is (703) 308-4609. The examiner can normally be reached on Monday, Tuesday and Thursday from 6 AM to 3:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Rose/LR  
September 9, 2003



**SHEP K. ROSE  
PRIMARY EXAMINER**